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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,238

04/16/2004

Alison B. Lukacsko

94902.256172

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12/27/2010

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EXAMINER

JAGOE, DONNA A

ART UNIT

PAPER NUMBER

1619

NOTIFICATION DATE

DELIVERY MODE

12/27/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/826,238	<b>Applicant(s)</b> LUKACSKO, ALISON B.	
	<b>Examiner</b> Donna Jagoe	<b>Art Unit</b> 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 45-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

***Claims 45-49 have been examined on the merits.***

Applicant's amendments and arguments filed 12 October 2010 are acknowledged and have been fully considered. Any rejection and/or objection not specifically addressed below in original or modified form is herein withdrawn.

### ***Response to Arguments***

Applicant points out that the "minimizing side effects" language was directed to the combination of oral glycopyrrolate with topical glycopyrrolate which permits a lower level of the oral therapeutic thereby lessening side effects caused by the oral drug. In response to this remark, it is noted that the features upon which applicant relies (i.e., "oral administration of glycopyrrolate") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant states that those of ordinary skill in the art understand that chronic fungal infections are extremely recalcitrant and a treatment that improves symptoms frequently fails to kill the infective organism. Once treatment is stopped, the fungus rebounds. In response, clearly, the reference does not state that the patient treated "rebounded" when treatment stopped. Further, the patient obtained satisfactory control of sweating and has not experienced any side effects. Wassenaar teaches that the 35 year old male patient with excessive sweating and chronic fungal infection, treated with

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glycopyrrolate (an ACQA) pads, had worked so well that they “changed his life”. His facial and groin sweating and improved markedly, and as a result, the chronic fungal infection of his groin and constant facial rash had both improved. Applicant states that “because Wassenaar does not claim the step of killing fungi and bacteria, it cannot be said to anticipate the invention. In response, the instant claims are drawn to administering to the skin surface of the human body, however the claims fall short of claiming “wherein the fungi and bacterial are killed”. “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus, the claiming of a new use, new function or unknown property to the component, required to be administered in the instantly claimed method which is inherently present in the prior art, does not necessarily make the claim patentable. Regarding the amendment to the claim drawn to “...wherein the therapeutically effective amount alone is able to ? fungi and bacteria on the skin” The claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts and as such, would not exclude other carriers such as alcohol that could kill dermatophytic fungi and bacteria. Further, the new limitation of instant claim 45 does not exclude the presence of other actives; it merely indicates that if one were to take the other actives out, the anticholinergic quaternary amine compound would still be effective to kill dermatophytic fungi and bacteria on the skin surface. There is no requirement that those other actives be excluded.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as indefinite because the claim recites the method “wherein the therapeutically effective amount alone is able to fungi and bacteria on the skin surface”. It is unclear what the therapeutically effective amount alone is able to do to the fungi and bacteria since the words “kill and inhibit” have been deleted from the claim. Correction is required.

The remaining claims are indefinite to the extent that they read on the rejected base claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 45-49 are rejected under 35 U.S.C. 102(a) as being anticipated by Wassenaar U.S. Patent No. 7,060,289 B2.

Wassenaar teaches the method of reducing excessive sweating and minimizing side effects (see abstract) comprising application of a topical formulation of glycopyrrolate (an anticholinergic quaternary amine) in an aqueous solution (column 7, line 47) in a concentration that is from 0.25% to 6% (column 8, lines 29-30). Wassenaar teaches a case study of a patient with excessive sweating of the forehead and groin that resulted in a facial rash and fungal infection. After two weeks of topical application (to the skin surface) the chronic fungal infection of his groin and facial rash had both improved (column 8, lines 32-49). Regarding the concentration of the formulation instantly claimed, the amount of glycopyrrolate of Wassenaar is between 0.25% and 6% which is encompassed by the instantly claimed 0.0001% to about 20 % or from about 0.05% to about 5%. The claim elements appear in Wassenaar in the same configurations; an aqueous solution of glycopyrrolate in overlapping concentrations, serving the same functions; applied topically, to achieve the results suggested in prior art; treatment of a fungal infection. With regard to instant claim 45, drawn to "killing and inhibiting dermatophytic fungi and bacteria responsible for skin infection and non-pathological body malodor" these elements are disclosed in Wassenaar wherein it teaches that a fungal groin infection was improved when a 1% and 1.5% solution was applied.

No claims are allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on (571) 272-0871. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/YVONNE L. EYLER/  
Supervisory Patent Examiner, Art Unit 1619

Donna Jagoe /D. J./  
Examiner  
Art Unit 1619

December 13, 2010